DEPARTMENT OF HEALTH AND HUMAN SERVICES
Public Health Service
Indian Health Service. Refer to: OHP/OEHE

INDIAN HEALTH SERVICE CIRCULAR 95-18

SAFE MEDICAL DEVICE ACT REPORTING POLICY

Sec.

1. Purpose This Circular, previously issued in 1993, directs **the method** by which the Indian Health Service (IHS) will comply with the Safe Medical Device Act (SMDA) of 1990. The requirement that the Area Director report all incidents within the Area to the Director, IHS, is eliminated. This information is a duplication of information provided to the Food and Drug Administration (FDA) and manufacturers.

   The IHS will report all deaths, serious illness, or injuries of patients, employees, or persons affiliated with the IHS that are caused or Suspected to be caused by a medical device, to the FDA and/or the manufacturer; see Exhibit A, FDA Form 3500A (6/93).

2. POLICY. Medical personnel and other employees of the IHS who become aware of information that reasonably suggests that a medical device has contributed to a patient's death, serious injury, or serious illness while being treated in an IHS or tribal facility will report the incident as directed by this circular. All IHS and tribal facilities are required by law to comply with the reporting *requirements* as specified by the implementing regulations of the SMDA.

Distribution: PSD 557 (Indian Health Mailing Key)
Date: October 17, 1995

3 . D E F I N I T I O N S .

A. Medical Device. An instrument, apparatus, contrivance, implant, in vitro reagent, or other similar *or* related article, 'including anycomponent; part,or, accessory, which is as follows

(1) Recognized in the official National Formulary, or in the United States Pharmacopeia, or any supplement to them.

(2) 1ntended for use in the diagnosis of disease or other condition, or in the cure, mitigation, treatment, or-prevention of disease in humans.

(3) Intended to affect the structure or any function of the human body, but does not achieve its primary intended purposes through chemical action within or on the human body and is not dependent upon being metabolized for the achievement of any of its intended principal purposes.

(4) Intended for use in the diagnosis of medical conditions-other than disease.

(5) Used for in vitro diagnosis, including those products regulated as drugs prior to 1976.

B. **Device-User Facility** A hospital, ambulatory-surgical center, nursing home; outpatient treatment facility, or outpatient diagnostic facility that it3 not a physician's office.

C. **Device Incident Files. or other information.** including medical files and patient records, in the possession of user facilities related to adverse events that may have been caused by a device.

D. **Medical Device Reporting** (MDR) Reportable Event The event for which a person required to report under the SMDA ha6 received or become aware of information that reasonably suggests that a device has or may have caused or contributed to a death, serious illness, serious injury, or Other significant adverse experience, as determined by the secretary by regulation to be necessary to be reported. This includes the failure of a diagnostic device if information reasonably suggests that a misdiagnosis or lack of diagnosis resulting from the failure has caused or would cause or contribute to a

death, Serious injury, or serious illness if the malfunction were to recur. This includes events due to user error or failure to service or maintain the device

E. **Serious Illness or Serious Injury**. An injury or illness that:

(1) Is life threatening.

(2) Results in permanent impairment of a body function or permanent damage to a body structure.

(3) Necessitates medical or surgical intervention to preclude permanent-impairment of a body function or permanent damage to a body structure.

F. **Contact Person** An employee of the user facility designated with the responsibility *for* implementing and managing the facility's medical device-reporting program, and with whom the FDA will conduct its correspondence relating to user facility 'reporting. Examples of individual6 who could be designated as a Contact Person include the facility risk manager, quality assurance coordinator, or safety officer.

G. Medical Personnel Physicians, nurses, biomedical engineers, technoiogists, and risk mangers employed by the facility. For the purposes of this circular, the term does not include independent contractors.

H. **Working Days**. Monday through Friday excluding Federal holidays.

4. AUTHORITY. The Safe Medical Devices Act of 1990 and the FDA regulation6 implementing the Act. The proposed medical device reporting (MDR) regulations were published in the Federal Register on November 29, 1991 (56FR 60024). The MDR Final Regulation is pending as of the date of this chapter.

5. RESPONSIBILITY.

A. Service unit.

(1) Any IHS employee, who witnesses, discovers, or otherwise becomes aware of information that reasonably Suggests that MDR Reportable Events have occurred, shall immediately report the incidents to

their supervisors or department heads or to the facility risk manager.

(2) The supervisor or department head mu&t immediately, report any incidents reported to them by employees to the designated Contact Person for the facility.

(3) Contact Person Responsibilities

a. The Contact Person shall have overall responsibility, for implementing and managing the facility's medical device reporting program. This responsibility shall include establishing and maintaining a facility-wide-system for documenting medical device incidents; providing training and education on the reporting program to all medical personnel; reviewing and analyzing all reported incidents; and completing and submitting appropriate reports to outside agencies. The Contact Person shall be the contact agent for the facility.

b. The Contact Person shall convene a team to investigate all incident6 involving unexpected death, serious injury or serious illness of patients to determine whether an MDR Reportable Event ha6 occurred. The results of the investigation should be reviewed by the Risk Management or other appropriate committee, which shall adopt recommendations *for* corrective action.

c. The Investigation Team shall consist of:

- The facility risk manager or quality assurance coordinator.
- The Clinical Director (if s/he is directly involved with the incident, the Service Unit Director will designate a substitute).
- The Director of Nursing (if s/he is directly involved with the incident, the Service Unit Director will designate a substitute).
- The Area Clinical Engineer (Area Biomedical Engineer) or facility Biomedical Engineer/Engineering Technician.
- The Safety Officer.

d. The Contact Person sha11 be responsible for-submitting appropriate reports to the FDA and/or the medical device manufacturer in accordance with Federal law and regulations

e. The Contact Person shall ensure that all data collected from the facility's medical device reporting program shall be incorporated into the facility wide incident reporting program. The information will be communicated to administration, the safety committee, Area Office, and all device users on a need-to-know basis. Patient identifiers will remain c o n f i d e n t i a l

The Contact Person shall be responsible for the development and upkeep of a Device Incident File for SMDA reportable incidents (see Investigation 6.B.6 of this circular)

(4) **The Attending Physician.**

The attending-physicianshall have the responsibility of informing the patient, and/or the patient's family whether or not a medical device has contributed to the death, serious illness, serious injury, or other significant adverse experience of the patient. timing and manner Of the notification is left to the discretion of the attending physician.

(5) The Clinical Director

The Clinical Director shall be responsible for the medical aspects of the investigation, i.e., determining the seriousness of the illness or injury as defined in the SMDA.

(6) **Facility Biomedical Engineer/Engineering Technician**

The facility Biomedical Engineer/Engineering Technician shall obtain relevant information regarding previously reported hazards, recalls, and problems with respect to incident-related devices through contact with the FDA.

(7) The Service Unit director

The Service Unit Director (or Public Law 93-638 Program Director) has the responsibility to ensure that his/her facility is in compliance with Federal SMDA regulations.

B. Area Office

The Area Clinical Engineer

(1) The Area Clinical Engineer shall play a key role in investigating incidents and evaluating the safety of In the absence of a facility Biomedical Engineer/Engineering Technician, these responsibilities shall be assumed by the Area Clinical Engineer

(2) The Area Clinical Engineer shall compile an Area-wide report for the Area Director on all incidents reported to the FDA. He/she shall inform other facilities if a problem with a medical device has Area-wide implications.

C. Privacy Act

The medical device reporting records are subject to the Privacy Act of 1974 and, as such, must be safeguarded and maintained in accordance with the INS Privacy Act System of Records 09-17-OO01 Health and Medical Records Systems, HHS/PHS/OHP

6. PROCEDURES.

A. General Reporting Requirements

(1) Any employee of an IHS facility who discovers, witnesses, or is made aware of a potential MDR Reportable Event shall immediately notify the attending physician, his/her supervisor, and the Contact Person of the facility.

Additionally, the individual must complete an incident report form.

(2) To ensure proper followup and investigation of the incident the person who reports the adverse medical device incident shall obtain the following information whenever possible:

a. Patient's name

b. Patient's health record number

c. Patient's location at time of incident

d Name of attending physician notified

e. Product name

f. Location of the product

g. Serial or lot number of the product

h. Model or catalog number

i. Name of the manufacturer, if known

j. Brief description of the incident

k. Condition of the patient before and after the incident

(3) Whenever possible. the person reporting the incident Shall secure the device and its packaging, if any.

(4) Within 24 hours of the suspected MDR Reportable Event, the person who reported the incident shall complete an Incident Report and forward the Incident Report to the facility Contact Person. The facility Contact Person will forward a copy of the report to the Area Clinical Engineer and the facility Biomedical Engineer/Engineering Technician.

B. Investigation.

(1) The Investigation Team shall conduct an investigation of the event to determine whether a -device caused or contributed to the event and how. Outside

specialists may be consulted if necessary The results of the investigation shall be reviewed by the quality assurance/risk management committee or other appropriate committee, which shall propose recommendations for corrective action.

(2) The attending physician who is informed of a medical device incident Shall examine the patient, evaluate the severity of the patients illness or injury related to the incident, record the patient's physical findings, and document in the patient's progress notes the occurrence of the suspected adverse medical device incident and any actions taken based on the examination.

(3) The Area Clinical Engineer or facility Biomedical. Engineer/Engineering Technician shall assist the' Contact Person with collecting the device information, service and history information, and other information required. They shall also assist in conducting an investigation of the device-related incident, evaluate the-safety of the device, and determine whether the device along with the relevant supplies, accessories, and packaging should be impounded, repaired, or returned to service.

(4) The Contact Person in conjunction with the Area Clinical Engineer or facility Biomedical Engineer/Engineering Technician will- conduct an investigation and determine whether similar equipment should be impounded or taken out of service. The investigation must be completed within 8-9 working days.

(5) At the conclusion Of the investigation, if it is determined that a device was a contributing factor in the death of, serious injury to or illness of a patient, the Contact Person will file the required information with the FDA and/or manufacturer.

(6) Each user facility will be required to keep record6 concerning medical device events. These files must contain records of any event that was investigated by the facility, whether or not it was determined to be a reportable event. Each facility shall establish a device incident file and maintain a record of any information, including any written or oral communication, received by the user facility concerning an event that is subject to reporting

under this part, Such information includes information that has been reviewed by the facility in the process of determining. what is a reportable event, including patient records.

A device user facility shall maintain copies of any records reguired by the SMDA for 2 years after the, date of submission of a report to the FDA and/or manufacturer.

c. Medical Device Reporting.

"The Contact Person shall be responsib1e for submitting appropriate reports to the FDA and/or the medical device manufacturer in accordance with Federal law and regulation. The law requires the following:

(1) Patient deaths must be reported to the FDA and the manufacturer within 10 *working* days of becoming aware that a device caused or contributed to the incident.

(2) Serious injuries or illnesses-must be reported to the medical device manufacturer (or to the FDA, if the manufacturer is unknown) within.10 working days of becoming aware that a device caused or contributed to the incident.

(3) Semi-annual *summaries* of reports must be submitted to the FDA by January 31, covering reports for the previous July 1 to December 31; and by July 31, covering reports for the previous January 1 to June 30. The Contact Person will be responsible for submitting the reports.

The summary shall include the following information: the identity of the facility; the device's name, serial number, lot number, and model number; the manufacturer's name and address; and a brief description of the event. If no incidents occur, semi-annual reports are not required.

(4) Reports should be submitted to the following address:

FDA
Center for Devices and Radiological Health
MDR User Report
P.O. Box 3002
Rockville, MD 20847-3002

Semi-annual reports should have "semi-annual Report" *written on* the lower left hand side of the envelope. The report should, be made by, the individual who is designated as the Contact Person.

(6) Reports that require notification of-the manufacturer Shall be mailed to the appropriate address when known. If no address is known or the manufacturer is unknown, the report will be mailed to the FDA.

Additionally, a copy of the report should be sent to the Area Clinical Engineer who will: compile an Area-wide Report for the Area Director and to inform *other* facilities if a problem with a medical device has Area-wide implications.

D. Trend Analysis.

The Contact Person in conjunction with the Safety Committee will be responsible for the trends analysis of medical device incidents, in accordance with the Joint Commission on Accreditation of Healthcars Organizations requirements. The, analysis should be shared with the governing body, Service unit director, directors Of all departments/services, and those responsible for Other monitoring activities, including risk management or quality assessment and improvement.

E. Written Procedures.

The Contact Person will maintain written procedures for the following areas:

(1) Training and education programs that focus on employee obligations, including how to identify and report events that may be subject to user facility reporting.

(2) Internal systems that provide for identification, communication, and evaluation of events that may be subject to reporting, including a standardized review procedure for determining when an event meets the criteria for reporting and mechanisms to ensure the timely transmission of completed reports.

(3) Documentation and record keeping requirements for incident information that was reviewed, all reports and information submitted to the FDA and/or

manufacturers, information that facilitates the submission of semi-annual reports, and systems that ensure access to information that facilitates timely followup and inspection by the FDA.

7. Reporting Forms .

Reporting *forms* may be found at Exhibit A, FDA Form 3500A (6/93), along with instructions to report device problems to FDA and/or manufacturers. The Office of Health Programs will ensure that all Areas are provided copies of the final reporting instrument.

8. Supersession. This Circular Supersedes IRS Circular 93-1, dated February 12, 1993.

9. Effective Date. This circular is effective upon date of signature by the Director, IHS.

Michael H. Trujillo, M.D., M.P.H.
Assistant Surgeon General
Director, Indian Health Service

(10/17/95)

Form Approved: OMB No. 0910-0291 Expires: 12/31/94
See OMB statement on reverse

MEDWATCH

THE FDA MEDICAL PRODUCTS REPORTING PROGRAM

For use by user-facilities, distributors and manufacturers for MANDATORY reporting

Page ___ of ___

Mfr report #

UF/Dist report #

FDA Use Only

A. Patient information

1. Patient identifier — In confidence
2. Age at time of event: or Date of birth:
3. Sex: ☐ female ☐ male
4. Weight: ___ lbs or ___ kgs

B. Adverse event or product problem

1. ☐ Adverse event and/or ☐ Product problem (e.g., defects/malfunctions)
2. Outcomes attributed to adverse event (check all that apply)
   - ☐ death ___ (mo/day/yr)
   - ☐ life-threatening
   - ☐ hospitalization – initial or prolonged
   - ☐ disability
   - ☐ congenital anomaly
   - ☐ required intervention to prevent permanent impairment/damage
   - ☐ other: ___
3. Date of event (mo/day/yr)
4. Date of this report (mo/day/yr)
5. Describe event or problem
6. Relevant tests/laboratory data, including dates
7. Other relevant history, including preexisting medical conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.)

C. Suspect medication(s)

1. Name (give labeled strength & mfr/labeler, if known)
   #1
   #2
2. Dose, frequency & route used
   #1
   #2
3. Therapy dates (if unknown, give duration) from/to (or best estimate)
   #1
   #2
4. Diagnosis for use (indication)
   #1
   #2
5. Event abated after use stopped or dose reduced
   #1 ☐ yes ☐ no ☐ doesn't apply
   #2 ☐ yes ☐ no ☐ doesn't apply
6. Lot # (if known)
   #1
   #2
7. Exp. date (if known)
   #1
   #2
8. Event reappeared after reintroduction
   #1 ☐ yes ☐ no ☐ doesn't apply
   #2 ☐ yes ☐ no ☐ doesn't apply
9. NDC # – for product problems only (if known)
   – –
10. Concomitant medical products and therapy dates (exclude treatment of event)

D. Suspect medical device

1. Brand name
2. Type of device
3. Manufacturer name & address
4. Operator of device
   - ☐ health professional
   - ☐ lay user/patient
   - ☐ other: ___
5. Expiration date (mo/day/yr)
6. model # ___
   catalog # ___
   serial # ___
   lot # ___
   other # ___
7. If implanted, give date (mo/day/yr)
8. If explanted, give date (mo/day/yr)
9. Device available for evaluation? (Do not send to FDA)
   ☐ yes ☐ no ☐ returned to manufacturer on ___ (mo/day/yr)
10. Concomitant medical products and therapy dates (exclude treatment of event)

E. Initial reporter

1. Name, address & phone #

Medication and Device Experience Report
(continued)

Refer to guidelines for specific instructions

Submission of a report does not constitute an admission that medical personnel, user facility, distributor, manufacturer or product caused or contributed to the event.

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
Public Health Service • Food and Drug Administration

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FDA Use Only

F. For use by user facility/distributor–devices only

1. Check one ☐ user facility ☐ distributor
2. UF/Dist report number
3. User facility or distributor name/address
4. Contact person
5. Phone Number
6. Date user facility or distributor became aware of event (mo/day/yr)
7. Type of report ☐ initial ☐ follow-up # ___
8. Date of this report (mo/day/yr)
9. Approximate age of device
10. Event problem codes (refer to coding manual) patient code ___ - ___ - ___ device code ___ - ___ - ___
11. Report sent to FDA? ☐ yes ___ (mo/day/yr) ☐ no
12. Location where event occurred ☐ hospital ☐ home ☐ nursing home ☐ outpatient treatment facility ☐ other: ___ (specify) ☐ outpatient diagnostic facility ☐ ambulatory surgical facility
13. Report sent to manufacturer? ☐ yes ___ (mo/day/yr) ☐ no
14. Manufacturer name/address

G. All manufacturers

1. Contact office – name/address (& mfring site for devices)
2. Phone number
3. Report source (check all that apply) ☐ foreign ☐ study ☐ literature ☐ consumer ☐ health professional ☐ user facility ☐ company representative ☐ distributor ☐ other: ___
4. Date received by manufacturer (mo/day/yr)
5. (A)NDA # ___ IND # ___ PLA # ___ pre-1938 ☐ yes OTC product ☐ yes
6. If IND, protocol #
7. Type of report (check all that apply) ☐ 5-day ☐ 15-day ☐ 10-day ☐ periodic ☐ initial ☐ follow-up # ___
8. Adverse event term(s)
9. Mfr. report number

H. Device manufacturers only

1. Type of reportable event ☐ death ☐ serious injury ☐ malfunction (see guidelines) ☐ other: ___
2. If follow-up, what type? ☐ correction ☐ additional information ☐ response to FDA request ☐ device evaluation
3. Device evaluated by mfr? ☐ not returned to mfr. ☐ yes ☐ evaluation summary attached ☐ no (attach page to explain why not) or provide code: ___
4. Device manufacture date (mo/yr)
5. Labeled for single use? ☐ yes ☐ no
6. Evaluation codes (refer to coding manual) method ___ - ___ - ___ - ___ results ___ - ___ - ___ - ___ conclusions ___ - ___ - ___ - ___
7. If remedial action initiated, check type ☐ recall ☐ repair ☐ replace ☐ relabeling ☐ other: ___ ☐ notification ☐ inspection ☐ patient monitoring ☐ modification/adjustment
8. Usage of device ☐ initial use of device ☐ reuse ☐ unknown
9. If action reported to FDA under 21 USC 360i(f), list correction/removal reporting number:
10. ☐ Additional manufacturer narrative and/or 11. ☐ Corrected data

MEDWATCH

THE FDA MEDICAL PRODUCTS REPORTING PROGRAM

INSTRUCTIONS FOR COMPLETING FDA FORM 3500A

For use by user facilities, distributors, and manufacturers
for MANDATORY reporting of adverse events and product problems
as designated in the applicable statutes and FDA regulations.

- All entries should be typed.
- Complete all sections that apply.
- To complete an item when information is not available, use:
  - NA for not applicable
  - NI for no information at this time (but may be available
  - UNK for unknown at a later date)
- Dates should be entered as month/day/year (e.g. June 3, 1993 = 06/03/93). If exact dates are unknown, provide the best estimate.
- For narrative entries, if the fields do not provide adequate space, attach an additional page(s), and indicate the appropriate section and block number next to the narrative continuation.
- All attached pages should be identified as page __ of __ and should display the user facility, distributor, or manufacturer report number in the upper right corner as applicable. Reports from user facilities, device distributors, and device manufacturers should include the firm's or facility's name in the upper right corner as well.
- If reporting more than two (2) suspect medications or one (1) suspect medical device per adverse event, use another copy of the form with only section C or section D filled in as appropriate.
- A computer-generated facsimile of the form may be submitted in lieu of the preprinted form if the submitter has received written preapproval from the MEDWATCH office. (see address on the last page). It is not necessary for this form to be generated in the same two-sided format as the preprinted form. A two page front-only form is acceptable.
- If no suspect medical device is involved in a reported adverse event, section G "all manufacturers" may be substituted for section D "suspect medical device" on the front of the form to enable the submission of a one page form.
- Adverse events with vaccines should not be reported on this form. Call 1-800-822-7967 for a copy of the VAERS form to report an adverse event associated with a vaccine.

(06/10/93)

FRONT PAGE: Report and Page Numbers

At the top of the front page, enter the page number and the total number of pages submitted (include attachments in the total) where the words "page __ of __" are indicated.

At the top-right corner of the front page, enter the manufacturer report number, the user-facility report number, or the distributor report number in the correspondingly labeled box. Complete both report numbers, if applicable, in order to cross-reference this report with a report from another source on the same event.

Mfr report # - This is the unique identifier used by the manufacturer for this report. For a follow-up report, the manufacturer report number is to be identical to the number assigned to the initial report. The manufacture report number is also entered in block G9 on the back of the form.

> **For device manufacturers:** The report number consists of three components: the firm's FDA registration number (for the site where the suspect medical device was manufactured, the calendar year, and a consecutive 5-digit number for each report filed that year by the manufacturer (e.g., xxxxxxx-1993-00001, xxxxxxx-1993-00002).
>
> **For drug and biologic manufacturers:** The report number (referred to as the control number on the old 1639 reporting form) can be any number the manufacturer chooses to uniquely identify the report. If the manufacturer is submitting a follow-up to a report originally obtained from FDA through the expedited transmission of a serious direct report, the "other" box in block G3 should be checked and the FDA-assigned central triage unit sequence number (CTU#) entered there.

UF/Dist report # - This is the unique identifier used by the user facility or the distributor for this report. For a follow-up report, the UF/Dist report number is to be identical to the number assigned to the initial report. The UF/DIST report number is also entered in block F2 on the back of the form.

> The user facility report number consists of three components: the facility's Health Care Financing Administration's (HCFA) number, the calendar year, and a consecutive 4-digit number for each report filed that year by the facility (e.g., xxxxxxx-1993-0001, xxxxxxx-1993-0002). If a facility does not have a HCFA number, the first report should be submitted with all zeros in the HCFA space, and FDA will assign a number to be used in future reports. If a facility has more than one HCFA number, the facility may choose any one of those numbers, but must use the same number for subsequent submissions.
>
> The distributor report number also consists of three components: the distributor ID number (registration number) assigned by FDA, the calendar year, and a consecutive 4-digit number for each report filed that year by the distributor (e.g., xxxxxxx-1993-0001, xxxxxxx-1993-0002).

SECTION A: PATIENT INFORMATION

Complete a separate form for each patient unless the report is on a medical device in which multiple patients were adversely affected through the use of the same device. In that case, indicate the number of patients in block B5 (event description) and complete blocks A1 - A3 for any one patient of the submitter's choice.

A1: **Patient identifier** - Provide the patient's initials or some other type of identifier that will allow both the submitter and the initial reporter (if different), to identify the report if contacted for follow-up. Do NOT use the patient's name or social security number.

The patient's identity is held in strict confidence by FDA and protected to the fullest extent of the law.

A2: **Age** - Enter the patient's birthdate, if known, or the patient's age at the time of event onset.

- o if the patient is 3 years or older, use years (e.g., 4 years).
- o if the patient is less than 3 years old, use months (e.g., 24 months).
- o if the patient is less than 1 month old, use days (e.g., 5 days).

Provide the best estimate if exact age is unknown.

If the adverse event is a congenital anomaly, use the age or birthdate of the child or the date pregnancy is terminated. If information is available as to the time during pregnancy when exposure occurred, provide that information in narrative block B5.

A3: **Sex** - Enter the patient's gender. If the adverse event is a congenital anomaly, report the sex of the child.

A4: **Weight** - Indicate whether the weight is in pounds (lbs) or kilograms (kgs). Make a best estimate if exact weight is unknown. If the adverse event is a congenital anomaly, use the weight of the child.

SECTION B: ADVERSE EVENT OR PRODUCT PROBLEM

B1: **Adverse event and/or product problem** - Choose the appropriate box. Both boxes should be checked if a product problem may have caused or contributed to the adverse event.

Adverse event: any incident where the use of a medication (drug or biologic), at any dose, or a medical device is suspected to have resulted in an adverse outcome in a patient. See the applicable statute, regulation, or guideline for the regulatory definition.

Product problem (e.g., defects/malfunctions): any report regarding the quality, performance or safety of any medical product. See the applicable statute, regulation, or guideline for the regulatory definition.

B2: **Outcomes attributed to adverse event** - Indicate all that apply to the reported event.

Death - only check if the death was an OUTCOME of the adverse event. Include the date if known. (DO NOT check if the patient happened to die while using a medical product but there was no suspected association between the death and the use of the product).

Life-threatening - Check if suspected that the patient was at substantial risk of dying at the time of the adverse event or if suspected that the use or continued use of the product might have resulted in the death of the patient.

Hospitalization (initial or prolonged) - Check if admission to the hospital or prolongation of hospitalization was a result of the adverse event. (e.g., do NOT check hospitalization if a patient in the hospital received a medical product and subsequently developed an otherwise nonserious adverse event, unless the adverse event prolonged the hospital stay.)

Disability - Check if the adverse event resulted in a significant, persistent or permanent change, impairment, damage, or disruption in the patient's body function/structure, physical activities and/or quality of life.

Congenital anomaly - Check if suspected that exposure to a medical product prior to conception or during pregnancy may have resulted in an adverse outcome in the child.

Required intervention to prevent permanent impairment or damage - Check if believed that medical or surgical intervention was necessary to preclude permanent impairment of a body function or to prevent permanent damage to a body structure that was suspected to be due to the use of a medical product.

Other - Check only if the other categories are not applicable to the report. Briefly describe the patient outcome in the space provided. The actual narrative of the event will be entered in block B5.

B3: **Date of the event** - Provide the best estimate of the date of first onset of the adverse event. For congenital anomalies, the date of birth or the date pregnancy is terminated should be used. If day is unknown, month and year are acceptable. If day and month are unknown, year is acceptable.

B4: **Date of this report** - The date the report is filled out.

B5: **Describe event or problem** -

For an adverse event: Describe the event in detail using the reporter's own words including a description of what happened and a summary of all relevant clinical information (medical status prior to the event, signs, symptoms, diagnoses, clinical course, treatment, outcome, etc.) If available and if relevant, include synopses of any office visit notes or the hospital discharge summary. To save time and space (and if permitted by the institution) attach copies of these records with any confidential information deleted. **Do not identify any patient, physician or institution by name. The initial reporter's identity should be provided in full in section E.**

Results of relevant tests and laboratory data should be entered in block B6. Preexisting medical conditions and other relevant history belong in block B7.

For a product problem: Describe the problem in sufficient detail so that the circumstances surrounding the defect or malfunction of the medical product can be understood. If available, the results of any evaluation of a malfunctioning device and, if known, any relevant maintenance/service information should be included in this section.

B6: **Relevant tests/laboratory data, including dates** - Include any relevant baseline laboratory data prior to the administration or use of the medical product, all laboratory data used in diagnosing the event and any available laboratory data/engineering analyses (for devices) that provide further information on the course of the event. Include any available pre- and post-event medication levels and dates (if applicable). Include a synopsis of any relevant autopsy, pathology, engineering or lab reports, if available. If preferred, copies of any reports may be submitted as attachments with all confidential information deleted. **Do not identify any patient, physician or institution by name. The initial's reporter's identity should be provided in full in section E.**

B7: **Other relevant history, including preexisting medical conditions** - If available, provide information on other known conditions in the patient (e.g., hypertension, diabetes, renal/hepatic dysfunction, etc.) and significant history (allergies, race or ethnic origin, pregnancy, smoking and alcohol use, drug abuse, etc.)

SECTION C: SUSPECT MEDICATION(S)

For adverse event reporting - a suspect medication is one that the initial reporter suspected was associated with the adverse event. In block C10 enter other concomitant medical products (drugs, biologics, medical devices, etc.) that the patient was using at the time of the event that are not the suspect product(s). Up to two (2) suspect medications may be reported on one form (#1 = first suspect product, #2 = second suspect product). Attach an additional form if there were more than two suspect medications for the reported adverse event.

C1: **Name** - Use the trade name as marketed. If unknown or if no trade name, use the generic name (with the manufacturer/labeler's name if known). For foreign reports, use the foreign trade name and the U.S. generic name.

C2: **Dose, frequency & route** - Describe how the product was used by the patient (e.g., 500mg QID orally or 10mg every other day IV). For reports involving overdoses, the amount of product used in the overdose should be listed, not the prescribed amount.

C3: **Therapy dates** - Provide the date administration was started (or best estimate) and the date stopped (or best estimate). If no dates are known, an estimated duration is acceptable (e.g., 2 years) or if therapy was less than one day then duration is appropriate (e.g., 1 dose or 1 hour for an IV).

C4: **Diagnosis for use** - Provide the indication for which the product was prescribed or used in this particular patient.

C5: **Event abated after use stopped or dose reduced** - In addition to checking the appropriate box, provide supporting lab tests and dates, if available, in block B6.

C6: **Lot #** - If known, include the lot number(s) with all product problem reports or any adverse event report with a biologic, or any therapeutic lack of effect with a medication.

C7: **Expiration date** - Include with all product problem reports.

C8: **Event reappeared after reintroduction** - In addition to checking the appropriate box, provide supporting lab tests and dates, if available, in block B6.

C9: **NDC #** - The national drug code is only required when reporting a drug product problem. It can be found on the product label and/or packaging. Zeros and dashes should be included as they appear on the label.

C10: **Concomitant medical products and therapy dates** - List and provide therapy dates for any other medical products (drugs, biologics, medical devices, etc.) that a patient was using at the time of the event. Do not include products used to treat the event.

SECTION D: SUSPECT MEDICAL DEVICE

For adverse event reporting - a suspect medical device is one that the initial reporter suspected was associated with the adverse event. In block D10, report other concomitant medical products (drugs, biologics, medical devices, etc.) that the patient was using at the time of the event that are not the suspect product(s). Attach an additional form if there was more than one suspect medical device for the reported adverse event.

D1: **Brand name** - The trade or proprietary name of the suspect medical device as used in product labeling or in the catalog. (e.g., Easyflo Catheter, Reliable Heart Pacemaker, etc.) This information may be on a label attached to a durable device, may be on a package of a disposable device, or may appear in labeling materials of an implantable device.

D2: **Type of device** - The generic or common name of the suspect medical device or a generally descriptive name (e.g., Foley catheter, heart pacemaker, patient restraint, etc.)

D3: **Manufacturer name & address** - If available, list the full name and mailing address of the manufacturer of the product.

D4: **Operator of device** - Indicate the type (not the name) of person operating or using the device on the patient at the time of the event.

Health professional =	physician, nurse, respiratory therapist, etc.
Lay user/patient =	person being treated, parent/spouse/friend of the patient
Other =	nurses aide, orderly, etc.

D5: **Expiration date** - If available. This date can often be found on the device itself or printed on the accompanying packaging.

D6: **Product identification numbers** - If available. Provide any or all identification numbers associated with the suspect device exactly as they appear on the device or labels. These numbers can be found on the device itself and/or in the accompanying literature and packaging. If the type of number is unknown, record the number on the line marked "other #".

Model # - the exact model number found on the device label or accompanying packaging, including any revision level information.

Catalog # - the exact number as it appears in the manufacturer's catalog or labeling.

Serial # - can be found on the device label. This number, assigned by the manufacturer should be specific to each device.

Lot # - can be found on the label or packaging material.

Other # - any other applicable identification number (e.g. component number product number, batch number, part number, etc.)

D7: **If implanted, give date** - For medical devices that are implanted in the patient provide the date (or the best estimate). If day is unknown, month and year are acceptable. If month and day are unknown, year is acceptable.

D8: **If explanted, give date** - If an implanted device was removed from the patient, provide the date (or the best estimate). If day is unknown, month and year is acceptable. If month and day are unknown, year is acceptable.

D9: **Device available for evaluation?** - To evaluate a reported problem with a medical device it is often critical for the manufacturer to be able to examine the suspect product. Indicate whether the device is available for evaluation. If it is not, indicate if product was returned to the manufacturer and, if so, the date of the return. (Do not send the device to FDA).

D10: **Concomitant medical products and therapy dates** - List and provide product names and therapy dates for any other medical products (drugs, biologics, medical devices, etc.) that a patient was using at the time of the event. Do not include products used to treat the event.

SECTION E: INITIAL REPORTER

Indicate the person who initially reported the adverse event to the user facility, distributor or manufacturer. For medical device reporting by user facilities, this person may or may not be the designated medical device reporting (MDR) contact.

E1: **Name, address & phone #** - Please provide the name, mailing address and phone number of the initial reporter who can be contacted to provide information on the event if follow up is necessary.

E2: **Health professional?** - Indicate whether the initial reporter is a health professional (e.g., physician, pharmacist, nurse, etc.) or not.

E3: **Occupation** - Indicate the type of health professional or reporter occupation, and include specialty if appropriate.

E4: **Initial reporter also sent report to FDA** - Indicate whether the initial reporter also notified or submitted a copy of this report to FDA. This information helps to track duplicate reports in the Agency data base.

BACK PAGE

At the top of the back page, enter the page number and the total number of pages submitted (include attachments in the total) where the words "page __ of __" are indicated.

SECTION F: FOR USE BY USER FACILITY/DISTRIBUTOR - DEVICES ONLY

This section is to be used by user facilities or distributors for the mandatory reporting of device adverse events and/or malfunctions to the FDA and/or the manufacturer. The use of form 3500A for reporting by user facilities and distributors is voluntary until the publication of the final regulation at which time the use of the form will be required.

A device user facility is defined by Section 519(b)(5)(A) of the Food, Drug, and Cosmetic Act as a "hospital, ambulatory surgical facility, nursing home, or outpatient treatment facility which is not a physician's office." FDA has proposed in a tentative final regulations, under Section 519(e)(5) of the act, to include, outpatient diagnostic facilities within the definition of user facility as well. Reporting by outpatient diagnostic facilities will be voluntary until FDA issues the final regulation implementing such requirement.

F1: **Check one** - Indicate whether the report is from a user facility or a device distributor.

F2: **UF/Dist report number** - Enter the complete number of the report exactly as entered in the upper right corner of the front page. For a follow-up report, the UF/Dist report number must be identical to the number assigned to the initial report. See instructions on page 2 for further explanation of UF/Dist report number.

F3: **User facility or distributor name/address** - Enter the full name and address of the user facility or distributor where report originated.

F4: **Contact person** - Enter the full name of the medical device reporting (MDR) contact person. This is the person designated by the facility's most responsible person as the device user facility/distributor contact for this requirement. FDA will conduct its MDR correspondence with this individual. The contact person may or may not be an employee of the facility. However, the facility and its responsible officials will remain the parties ultimately responsible for compliance with the requirement.

F5: **Phone number** - Enter the phone number of the medical device reporting (MDR) contact person.

F6: **Date user facility or distributor became aware of event** - Enter the date that the user facility's medical personnel or the distributor became aware that the device may have caused or contributed to the reported event.

User facilities are deemed to "become aware" of information that triggers reporting requirements only when they have sufficient information to make a determination that a report is required. Distributors, however, serve as a conduit of information submitted to them, and therefore, are deemed to become "aware" of information that triggers reporting requirements on the date they receive a report.

F7: **Type of report** - Check the appropriate box to identify the type of report being filed, i.e. an initial report of an event or a follow-up to a previously submitted report.

If a follow-up report, make sure that the UF/Dist report number for the previously submitted initial report is recorded in block F2. In the blank provided in block F7, record the appropriate sequence of follow-up to that particular initial report (e.g., first follow-up report = follow-up #1, second follow-up report = follow-up #2, etc.).

Follow-up reports should not repeat material that was submitted in the initial report but should only provide additional or corrected information on the previously reported event.

F8: **Date of this report** - Enter the date that the user facility or distributor forwards the report to FDA and/or the manufacturer.

F9: **Approximate age of device** - Enter the age of the device or a best estimate.

F10: **Event problem codes (refer to coding manual)** - Enter up to three patient and three device codes that most accurately describe the event.

F11: **Report sent to FDA?** - By statue or regulation, user facilities and distributors must submit reports of certain device-associated adverse events to FDA.

A user facility must submit to FDA reports of

1. deaths suspected of being device-related
2. serious injuries suspected of being device-related if the manufacturer is unknown

A distributor must submit to FDA reports of

1. deaths suspected of being device-related
2. serious injuries suspected of being device-related

See applicable statute, regulations, or guidelines for further explanation of reportable events.

F12: **Location where event occurred** - Check the location of the actual occurrence of the event.

F13: **Report sent to manufacturer?** - By statute or regulation, user facilities and distributors must submit reports of certain device-associated adverse events to the manufacturer of the device.

A user facility must submit to the manufacturer, if known, reports of

1. deaths suspected of being device related
2. serious injuries suspected of being device related

a distributor must submit to the manufacturer reports of

1. deaths suspected of being device related
2. serious injuries suspected of being device related
3. certain malfunctions

See applicable statute, regulations, or guidelines for further explanation of reportable events.

F14: **Manufacturer name/address** - Enter full name and address of the device manufacturer to which the report was sent.

SECTION G: ALL MANUFACTURERS

This section is to be filled out by all manufacturers.

NOTE: If a drug or biologic manufacturer is reporting an adverse event in which no suspect medical device is involved, section G may be identically reproduced in place of Section D on the front of the form so that a one page form may be submitted.

G1: **Contact office - name/address (& mfring site for device)** - Enter the full name and address of the manufacturer. The name of the contact person may also be included. The name and address of the manufacturing site of the device should be included if different from the contact office. Device manufacturers should include the name of the medical device reporting (MDR) contact person.

G2: **Phone number** - Enter the phone number of the contact office.

G3: **Report source** - Check the box(s) that most accurately describes how the manufacturer contact office found out about the reported adverse event.

Foreign - Foreign sources include foreign governments, foreign affiliates of the application holder, foreign licensors and licensees, etc. The country of origin should be included.

Study - Postmarketing, clinical trial, surveillance, or other study which involves a systematic collection of adverse events from a protocol designed specifically to investigate product safety.

Literature - If the report source is the scientific literature or an unpublished manuscript, a copy of the article or manuscript must be attached. Foreign language articles should be translated. A separate 3500A form is to be completed for each identifiable patient described in the article or manuscript.

Consumer - (including attorneys). Generally, additional information should be sought from the treating health care provider. A determined effort should be made to obtain additional detailed information from health professionals for all serious reactions initially reported by consumers. When this additional information is obtained, the follow-up report should check health professional rather than consumer in block G3.

Health professional - self-explanatory.

User facility - User facility should be checked if the manufacturer received the report from the MDR contact in a user facility as defined in section F.

Company representative - Company representative should be checked if s(he) reported the event to the contact office based on information from a health professional. The health professional should be listed as the initial reporter on the front page of the form.

Distributor - Distributor should be checked if the manufacturer received the report from a distributor of the suspect product.

Other - any source not covered by the previous categories. For drug and biologic manufacturers - if submitting a followup to a report originally obtained from FDA through the expedited transmission of a serious direct report, this box should be checked and the FDA-assigned central triage unit sequence number (CTU#) entered in the space provided.

G4: Date received by manufacturer - The date received by the manufacturer means the date when the applicant, manufacturer, corporate affiliate, etc. initially received information that an adverse event or medical device malfunction occurred. This would apply to a report received anywhere in the world. For follow-up reports, use the date that the follow-up information was received.

G5: This block is for use by drug and biologic manufacturers only - provide whatever information is applicable to the suspect medication identified in section C.

If the report lists two products by the same applicant as suspect, the report should be submitted to the application file of the product thought by the initial reporter most likely to be the cause of the adverse event. If they are equally suspect, the report should be submitted to the application file of the product that is first alphabetically.

(A)NDA # - the abbreviated new drug application or the new drug application number. The report should be filed to the first approved NDA if a product has several NDA's and the specific one cannot be determined.

IND # - the investigational new drug application number.

PLA # - the product license application number.

Pre-1938 - check the box if the suspect medication is a prescription product marketed prior to 1938 and does not have an approved application.

OTC - product check the box if the suspect medication can be purchased over-the-counter.

G6: If IND, protocol # - This block is for use by drug and biologic manufacturers only. If the form is being used as a 10-day IND safety report, enter the protocol number.

G7: Type of report - Check all that apply to reported event.

5-day - Devices: See applicable statute, regulations, and guidelines.

10-day - Drugs and Biologics: For reports of serious and unexpected adverse events derived from a study conducted under an investigational new drug application (IND), as specified in the applicable regulations and guidelines.

15-day - Devices: See applicable statute, regulations, and guidelines.

Drugs and Biologics: For reports of serious and unexpected adverse events, as specified in the applicable regulations and guidelines.

Periodic - Drugs and Biologics: For reports of serious labeled and non-serious (labeled and unlabeled) adverse events as specified in the applicable regulations and guidelines.

Initial - Check if the report is the first submission of a report.

Follow-up - Check if the report is a follow-up to a previously submitted report. Follow-up reports on devices should not repeat material that was submitted in the initial report but should only provide additional or corrected information on the previously reported event. Follow-up reports on drugs and biologics should contain information that was submitted in the original report if the information is still correct.

If a follow-up report, make sure that the manufacturer report number for the previously submitted initial report is recorded in block G9. In the blank provided in block G7, record the appropriate sequence of follow-up to that particular initial report (e.g., first follow-up report = follow-up #1, second follow-up report = follow-up #2, etc.).

For drug and biologic manufacturers - if submitting a follow-up to a report originally obtained from FDA through the expedited transmission of a serious direct report, the "other" box in block G3 should be checked and the FDA assigned central triage unit sequence number (CTU#) entered there.

G8: Adverse event term(s) - For use by drug and biologic manufacturers only. Include a list of adverse event terms that most accurately characterize the adverse event described in narrative format in block B5. Terms should be listed with the most important term(s) first. The terminology may be an accepted standard (e.g., COSTART or WHOART), a verbatim term or the manufacturer's own terminology.

G9: Mfr. report number - Enter the manufacturer report number exactly as it appears in the upper right corner of the front page. For a follow-up report, the manufacturer report number is to be identical to the number assigned to the initial report. See instructions on page 2 for further explanation of manufacturer report number.

SECTION H: DEVICE MANUFACTURERS ONLY

H1: Type of reportable event - Check the appropriate box. These choices represent the categories of events that device manufacturers are required to report.

Death - only check if the death was an OUTCOME of the adverse event.

Serious injury - an adverse event that is life-threatening; results in permanent impairment of a body function or permanent damage to the body structure; or necessitates medical or surgical intervention to preclude impairment of a body function or permanent damage to

capital equipment, the "no" box is the appropriate selection.

H6: **Evaluation codes (refer to coding manual)** - Enter up to four codes for each category of evaluation methods, evaluation results, and conclusions.

H7: **If remedial action initiated, check type** - Indicate the applicable action(s). If other, specify the type of action in the space provided. Most of these terms are defined or further explained in the act or in the FDA regulations concerning remedial action (see 21 U.S.C. 360h and 21 CFR part 7 and 803).

H8: **Usage of device** - Indicate whether the use of the suspect device was the initial use, a reuse or if unknown.

H9: **If action reported to FDA under 21 U.S.C. 360i(f), list correction/removal reporting number** - Enter the number that FDA assigned to the corrective action.

H10: **Additional manufacturer narrative** - Enter any additional information, evaluation, or clarification of data presented in previous sections. Do not duplicate information that has already been provided elsewhere.

H11: **Corrected data** - Enter any data that corrects information presented elsewhere on the form or that was previously submitted. Indicate the block number of the data being corrected.

This block is intended to be used to indicate changes to incorrect information regarding the reported event. It refers to corrected information in the form and not to any corrections the manufacturer may have made to the medical device or to data supporting the safety or efficacy of the device.

a body structure.

Malfunction - see the guidelines.

Other - specify the type of report in the space provided. This option is intended to capture reports that a manufacturer believes the agency should be aware of that ~~are not~~ covered by death, serious injury, or malfunction as these terms are defined by statute, regulation or guidelines.

This "other" category can be used to notify FDA of a MDR reportable event for which a corrective action or removal was taken. Section 519(f)(1) of the act states that no report of corrective action or removal is required if it has been reported per section 519(a) of the act. Do not use this form to report a corrective action or removal if no MDR report is required.

This "other" category can also be used to report "other significant adverse device experience as determined by the Secretary to be necessary to be reported" as specified under the Medical Device Amendments of 1992.

H2: **If follow-up, what type?** - Check the box(s) that most accurately describe the nature of the follow-up report.

Correction - changes to previously submitted information.

Additional information - information concerning the event that was not provided in the initial report because it was not known/available when the report was originally submitted.

Response to FDA request - additional information requested by FDA concerning the device/event.

Device evaluation - evaluation/analysis of device.

H3: **Device evaluated by mfr?** - Indicate if an evaluation was made of the suspect device. If an evaluation was conducted attach a summary of the evaluation and check the box. If an evaluation was not conducted, explain why not on an attached page or in block H10 or provide the appropriate code in the space provided. (See coding manual for appropriate codes.)

H4: **Device manufacture date** - Enter the month and year of manufacture of the suspect medical device.

H5: **Labeled for single use?** - Indicate whether the device was labeled for single use or not. If the question is not relevant to the device being reported, such as